REMARKS

Claims 1-46 are in the application. Claims 1-19 are directed to the elected invention. Claims 20-46 are directed to non-elected inventions and may be canceled by the Examiner upon the allowance of the claims directed to the elected invention.

The recent personal interview so courteously granted the undersigned and Dr. Mary Reppy by Examiner Tran is hereby noted with appreciation.

Claims 1-2 and 9-13 were rejected under 35 U.S.C. §102(b) as being anticipated by Reichert et al. (J. Am. Chem. Soc., 1995, 117; 829-830). As discussed during the above-mentioned interview, Reichert et al. do not anticipate the above claims since, among other things, Reichert et al. does not even remotely suggest detecting a change in fluorescence as required by the present invention. The technique of Reichert et al. relies upon a change in color, not a measurement of a change in fluorescence. Also the comment in the office action concerning Reichert et al that "the solution changes to a pink or orange color (the polydiacetylene of the array in the non-fluorescent form)" is not correct. Reichert et al. do not refer to the pink or orange color as being the non-fluorescent form. In fact, a pink or orange colored polydiacetylene is generally a fluorescent form of the polydiacetylene. At the above-mentioned interview, Examiner Tran agreed that Reichert et al did not anticipate the present invention.

Reichert et al. fail to anticipate the present invention. In particular, anticipation requires the disclosure, in a prior art reference, of each and every recitation as set forth in the claims. *See Titanium Metals Corp. v. Banner*, 227 USPQ 773 (Fed. Cir. 1985), *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986), and *Akzo N.V. v. U.S. International Trade Commissioner*, 1 USPQ2d 1241 (Fed. Cir. 1986).

There must be no difference between the claimed invention and reference disclosure for an anticipation rejection under 35 U.S.C. 102. *See Scripps Clinic and Research Foundation v. Genetech, Inc.*, 18 USPQ2d 1001 (CAFC 1991) and *Studiengesellschaft Kohle GmbH v. Dart Industries*, 220 USPQ 841 (CAFC 1984).

Claims 1-19 were rejected under 35 USC 103 (a) as being unpatentable over U.S. 5,415,999 Saul, et al., in view of US patent 6,180,135 B1 to Charych et al. These cited references do not render obvious the present invention. In particular, the claims under

consideration relate to detecting an analyte in a sample by contacting the sample to be tested with a three–dimensional array that comprises a polydiacetylene backbone and a substrate wherein the substrate has direct affinity for an analyte or is capable of binding to an analyte or is capable of reacting with an analyte. An analyte when present causes a change in fluorescence of the polydiacetylene backbone. The change in fluorescence is then detected to thereby indicate the presence of an analyte.

As discussed in the specification measuring the change in fluorescence of the array can be a more sensitive test than monitoring by color change. The increase in sensitivity is crucial for providing detection systems to have actual practical utility as a sensor for many applications where monitoring color change would not be satisfactory. For instance, the slope of change for the fluorescence measurements is significantly different from that for colorimetric measurements as clearly illustrated in Fig. 3 in this application, which further supports the improved results achievable by the present invention

Moreover, as discussed in the specification, the assay method of the present invention makes possible a continuous monitoring of the binding or the interaction of an analyte. Also, since no wash steps are required in the technique of the present invention, the method is relatively simple and inexpensive to carry out.

U.S. patent 5,415,999 to Saul et al, fails to suggest or render obvious the present invention since, among other things, as recognized by the Examiner, Saul et al., fails to suggest or disclose a three-dimensional array of a polydiacetylene backbone or, according to preferred aspects of the present invention, an array that is in the form of the liposomes or tubules (see claims 2, 11 and 13).

Charych, et al., fails to overcome the above-discussed efficiencies of Saul, et al., with respect to rendering obvious the present invention. In particular Charych, et al., does not relate to using fluorescence but instead relates to a method that monitors color change of a three-dimensional array of a polydiacetylene backbone. Nothing whatsoever in Charych et al., would suggest that the three-dimensional array could be used in a method that detects the change in fluorescence of the three-dimensional array. Charych et al suggest a colorimetric change of polydiacetylene liposomes from blue or purple to red (pink) or orange, respectively, in response to the analyte binding or reacting with a substrate incorporated in the liposomes. Since the

technique suggested by Saul et al., requires starting with a red fluorescent film it would be counterintuitive to employ the non-fluorescent three-dimensional array suggested by Charych et al., in the method of Saul et al. Accordingly, the prior art lacks any motivation to substitute the polydiacetylene three-dimensional arrays employed by Charych et al., in the method of Saul et al. In fact, if anything, the cited art actually leads from the present invention.

Concerning this rejection of the claims, as discussed during the above-mentioned interview, attached is a Declaration under 37 C.F.R. 1.132 by Dr. Mary Reppy, a coinventor of this application that states "to the best of my knowledge, prior to the present invention, such 3-dimensional arrays (i.e., 3-dimensional arrays comprising a polydiacetylene backbone) have not been used or discussed as being useful, at a time prior to the present invention, in a method for detecting an analyte in a sample by detecting a change in fluorescence as recited in the claims of this application under consideration."

Moreover, knowing that the polydiacetylene that Saul et al suggest is fluorescent does not imply that the form of polydiacetylene that Charych suggests would be non-fluorescent while the other form would be fluorescent. There is nothing in either Charych or Saul that would suggest that a change in fluorescence, if any, from a blue to red form of a three-dimensional array of a polydiacetylene backbone would be of sufficient magnitude for the purpose of detecting analytes.

In addition, Claim 9 which is directed to that aspect of the present invention wherein the polydiacetylene is in the non-fluorescent form is non-obvious since Saul et al., requires a polydiacetylene film that is in the fluorescent form to be suitable for the technique suggested therein. Accordingly, use of a non-fluorescent form would not be suitable for the express purposes of Saul et al.

Discussion of Case Law

The mere fact that cited art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the cited art suggest the desirability of the modification. No such suggestion appears in the cited art in this matter. The Examiner's attention in kindly directed to *In re Lee* 61 USPQ 2d 1430 (Fed. Cir. 2002) *In re Dembiczak et*

al. 50 USPQ2d. 1614 (Fed. Cir. 1999), *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984), *In re Laskowski*, 10 USPQ2d. 1397 (Fed. Cir. 1989) and *In re Fritch*, 23, USPQ2d. 1780 (Fed. Cir. 1992).

In Dembiczak et al., supra, the Court at 1617 stated: "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc., v. M3 Sys., Inc., 157 F.3d. 1340, 1352, 48 USPQ2d. 1225, 1232 (Fed. Cir. 1998) (describing 'teaching or suggestion motivation [to combine]' as in 'essential evidentiary component of an obviousness holding'), In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d. 1453, 1459 (Fed. Cir. 1998) ('the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them');...".

Also, the cited art lacks the necessary direction or incentive to those or ordinary skill in the art to render under 35 USC 103 sustainable. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention needed to sustain a rejection under 35 USC 103. See *Diversitech Corp. v. Century Steps, Inc.* 7 USPQ2d 1315 (Fed. Cir. 1988), *In re Mercier*, 185 USPQ 774 (CCPA 1975) and *In re Naylor*, 152 USPQ 106 (CCPA 1966).

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d. 1923 (Fed. Cir. 1990), *In re Antonie*, 195, USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

No property can be ignored in determining patentability and comparing the claimed invention to the cited art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 22001-00005-US from which the undersigned is authorized to draw.

Respectfully submitted

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